## **Introduced by Senator Lara**

February 26, 2015

An act to amend Section 11165 of add Section 11165.4 to the Health and Safety Code, relating to controlled substances.

## LEGISLATIVE COUNSEL'S DIGEST

SB 482, as amended, Lara. Controlled substances: reporting. Controlled substances: CURES database.

Existing law classifies certain controlled substances into designated schedules. Existing law requires the Department of Justice to maintain the Controlled Substance Utilization Review and Evaluation System (CURES) for the electronic monitoring of the prescribing and dispensing of Schedule II, Schedule III, and Schedule IV controlled substances by all practitioners authorized to prescribe or dispense these controlled substances. Existing law requires dispensing pharmacies and clinics to report specified information for each prescription of a Schedule II, Schedule III, or Schedule IV controlled substance to the department.

This bill would require all prescribers, as defined, prescribing a Schedule II or Schedule III controlled substance, and all dispensers, as defined, dispensing a Schedule II or Schedule III controlled substance, to consult a patient's electronic history in the CURES database before prescribing or dispensing the controlled substance to the patient for the first time. The bill would also require the prescriber to consult the CURES database at least annually when the prescribed controlled substance remains part of the patient's treatment. The bill would prohibit prescribing an additional Schedule II or Schedule III controlled substance to a patient with an existing prescription until the

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prescriber determines that there is a legitimate need for the controlled substance.

The bill would make the failure to consult a patient's electronic history in the CURES database a cause for disciplinary action by the prescriber's or dispenser's licensing board and would require the respective licensing boards to notify all licensees authorized to prescribe or dispense controlled substances of these requirements. The bill would provide that a prescriber or dispenser is not in violation of these requirements during any time that the CURES database is suspended or not accessible, or during any time that the Internet is not operational. The bill would make its provisions operative upon the Department of Justice's certification that the CURES database is ready for statewide use.

Existing law classifies certain controlled substances into designated schedules. Existing law requires the Department of Justice to maintain the Controlled Substance Utilization Review and Evaluation System (CURES) for the electronic monitoring of the prescribing and dispensing of Schedule II, Schedule III, and Schedule IV controlled substances by all practitioners authorized to prescribe or dispense these controlled substances. Existing law requires dispensing pharmacies and clinics to report specified information for each prescription of a Schedule II, Schedule III, or Schedule IV controlled substance to the department, no more than 7 days after the controlled substance was dispensed.

This bill would specify that the dispensing pharmacies and clinics are required to report the specified information to the department no more than 7 business days after the controlled substance was dispensed.

Vote: majority. Appropriation: no. Fiscal committee: no-yes. State-mandated local program: no.

The people of the State of California do enact as follows:

- 1 SECTION 1. Section 11165.4 is added to the Health and Safety 2 Code, to read:
- 3 11165.4. (a) A prescriber shall access and consult the CURES
- 4 database for the electronic history of controlled substances
- 5 dispensed to a patient under his or her care before prescribing a
- 6 Schedule II or Schedule III controlled substance for the first time
- 7 to that patient and at least annually when that prescribed
- 8 controlled substance remains part of his or her treatment. If the
- 9 patient has an existing prescription for a Schedule II or Schedule

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III controlled substance, the prescriber shall not prescribe an additional controlled substance until the prescriber determines that there is a legitimate need for that controlled substance.

- (b) A dispenser shall access and consult the CURES database for the electronic history of controlled substances dispensed to a patient under his or her care before dispensing a Schedule II or Schedule III controlled substance for the first time to that patient. If the patient has an existing prescription for a Schedule II or Schedule III controlled substance, the dispenser shall not dispense an additional controlled substance until the dispenser checks the CURES database.
- (c) Failure to consult a patient's electronic history as required by subdivision (a) or (b) is cause for disciplinary action by the respective licensing board of the prescriber or dispenser. The licensing boards of all prescribers and dispensers authorized to write or issue prescriptions for controlled substances shall notify these licensees of the requirements of this section.
- (d) Notwithstanding any other law, a prescriber or dispenser is not in violation of this section during any period of time in which the CURES database is suspended or not accessible or any period of time in which the Internet is not operational.
- (e) This section shall not become operative until the Department of Justice certifies that the CURES database is ready for statewide use.
- (f) For purposes of this section, the following terms shall have the following meanings:
- (1) "Dispenser" means a person who is authorized to dispense a controlled substance under Section 11011.
- (2) "Prescriber" means a health care practitioner who is authorized to write or issue prescriptions under Section 11150, excluding veterinarians.
- (g) A violation of this section shall not be subject to the provisions of Section 11374.
- SECTION 1. Section 11165 of the Health and Safety Code is amended to read:
- 11165. (a) To assist health care practitioners in their efforts to ensure appropriate prescribing, ordering, administering, furnishing, and dispensing of controlled substances, law enforcement and regulatory agencies in their efforts to control the diversion and resultant abuse of Schedule II, Schedule III, and

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Schedule IV controlled substances, and for statistical analysis, 1 2 education, and research, the Department of Justice shall, contingent 3 upon the availability of adequate funds in the CURES Fund, 4 maintain the Controlled Substance Utilization Review and 5 Evaluation System (CURES) for the electronic monitoring of, and 6 Internet access to information regarding, the prescribing and 7 dispensing of Schedule II, Schedule III, and Schedule IV controlled 8 substances by all practitioners authorized to prescribe, order, 9 administer, furnish, or dispense these controlled substances.

- (b) The Department of Justice may seek and use grant funds to pay the costs incurred by the operation and maintenance of CURES. The department shall annually report to the Legislature and make available to the public the amount and source of funds it receives for support of CURES.
- (c) (1) The operation of CURES shall comply with all applicable federal and state privacy and security laws and regulations.
- (2) CURES shall operate under existing law to safeguard the privacy and confidentiality of patients. Data obtained from CURES shall only be provided to appropriate state, local, and federal public agencies for disciplinary, civil, or criminal purposes and to other agencies or entities, as determined by the Department of Justice, for the purpose of educating practitioners and others in lieu of disciplinary, civil, or criminal actions. Data may be provided to public or private entities, as approved by the Department of Justice, for educational, peer review, statistical, or research purposes, provided that patient information, including any information that may identify the patient, is not compromised. Further, data disclosed to an individual or agency as described in this subdivision shall not be disclosed, sold, or transferred to a third party. The Department of Justice shall establish policies, procedures, and regulations regarding the use, access, evaluation, management, implementation, operation, storage, disclosure, and security of the information within CURES, consistent with this subdivision.
- (d) For each prescription for a Schedule II, Schedule III, or Schedule IV controlled substance, as defined in the controlled substances schedules in federal law and regulations, specifically Sections 1308.12, 1308.13, and 1308.14, respectively, of Title 21 of the Code of Federal Regulations, the dispensing pharmacy, elinic, or other dispenser shall report the following information to

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the Department of Justice as soon as reasonably possible, but not more than seven business days after the date a controlled substance is dispensed, in a format specified by the Department of Justice:

- (1) Full name, address, and, if available, telephone number of the ultimate user or research subject, or contact information as determined by the Secretary of the United States Department of Health and Human Services, and the gender, and date of birth of the ultimate user.
- (2) The prescriber's category of licensure, license number, national provider identifier (NPI) number, if applicable, the federal controlled substance registration number, and the state medical license number of any prescriber using the federal controlled substance registration number of a government-exempt facility.
- (3) Pharmacy prescription number, license number, NPI number, and federal controlled substance registration number.
- (4) National Drug Code (NDC) number of the controlled substance dispensed.
  - (5) Quantity of the controlled substance dispensed.
- (6) International Statistical Classification of Diseases, 9th revision (ICD-9) or 10th revision (ICD-10) Code, if available.
  - (7) Number of refills ordered.

- (8) Whether the drug was dispensed as a refill of a prescription or as a first-time request.
  - (9) Date of origin of the prescription.
  - (10) Date of dispensing of the prescription.
- (e) The Department of Justice may invite stakeholders to assist, advise, and make recommendations on the establishment of rules and regulations necessary to ensure the proper administration and enforcement of the CURES database. All prescriber and dispenser invitees shall be licensed by one of the boards or committees identified in subdivision (d) of Section 208 of the Business and Professions Code, in active practice in California, and a regular user of CURES.
- (f) The Department of Justice shall, prior to upgrading CURES, consult with prescribers licensed by one of the boards or committees identified in subdivision (d) of Section 208 of the Business and Professions Code, one or more of the boards or committees identified in subdivision (d) of Section 208 of the Business and Professions Code, and any other stakeholder identified by the department, for the purpose of identifying

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- 1 desirable capabilities and upgrades to the CURES Prescription
- 2 Drug Monitoring Program (PDMP).
- 3 (g) The Department of Justice may establish a process to educate
- 4 authorized subscribers of the CURES PDMP on how to access and
- 5 use the CURES PDMP.